THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

25 OCT 1996

HEALTH AFFAIRS

Joshua Lederberg, Ph.D.
Rockefeller University
Founder's Hall
1230 York Avenue, Room 402
New York, New York 10021

Dear Dr. ~~Lederberg~~ Josh:

As you are well aware, one of the most important issues facing the Department of Defense is protection of U.S. Forces against the very real threat of biological weapons. Within this context, the DOD is evaluating a vaccination policy for immunizing its personnel against *Bacillus anthracis*, the etiologic agent of anthrax. This agent is considered to be one of the premier biological warfare threats because of such characteristics as its capability to create high casualty levels over a wide area of the battlefield, its ease of production, and its environmental stability.

The licensed Anthrax vaccine manufactured by the Michigan Biologic Products Institute relies principally on the presence in the vaccine preparation of the protective antigen (PA) protein of *B. anthracis* to stimulate an immune response in humans that is believed to be protective against the infectious organism. This vaccine has demonstrated protective efficacy against highly lethal aerosol challenge in a non-human primate model.

A concern, however, that must be addressed is the possibility that an adversary could develop, by genetic engineering or other means, an organism capable of circumventing the protective effect provided by this vaccine. It is our understanding that this is deemed an unlikely event, based on the important biological function that the native PA protein serves during the infection process. But it is important for us to understand, as clearly as possible, the potential for such a risk.

May I therefore impose on your unmatched expertise in these matters to provide us with a perspective of the risk of genetic manipulation of the etiologic agent to produce an organism that could defeat our current vaccine. I express my sincerest gratitude for your willingness to help us resolve this pressing matter.

Sincerely,

Stephen C. Joseph, M.D., M.P.H.